CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-366

CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. #6

2. ANDA #75-366

3. NAME AND ADDRESS OF APPLICANT

Eon Labs Manufacturing, Inc.
Attention: Sadie M. Ciganek
227-15 North Conduit Avenue
Laurelton, NY 11413

Phone: 718-276-8607
Fax: 718-949-3120

4. LEGAL BASIS FOR SUBMISSION

The firm certifies that there is no patent for the reference listed drug. The New Chemical Entity exclusivity expired on 10/30/97, and the Orphan Drug Exclusivity will expire on 10/30/99. The product will not be marketed prior to 10/30/99.

Innovator: Berlex Laboratories -Betapace®(NDA 19-865)

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME

Sotalol Hydrochloride Tablets

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:

Original application: 4/13/98
Refusing to File Letter: 5/12/98
FDA acknowledgment: 6/10/98
Amend 1/22/99 to N/A (MINOR) letter 12/31/98
Amend 4/5/99 to N/A (MINOR) letter 3/8/99
Telephone Amendment 4/30/99 (see Memo dated 4/29/99)
Tentative Approval 7/26/99
Amendment 8/13/99
Amendment 9/7/99 (label)
Telephone Amendment 10/15/99 (sample validation)
Amendment 2/4/00
Telephone Amendment 3/15/00

10. PHARMACOLOGICAL CATEGORY
Antiarrhythmic

11. Rx or OTC
Rx

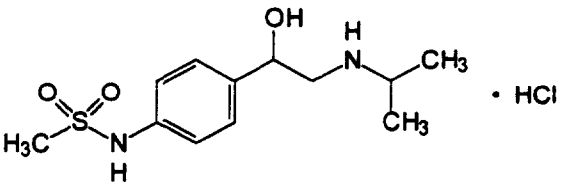
12. RELATED IND/NDA/DMF(s) See under #37 DMF CHECKLIST

13. DOSAGE FORM Tablets

14. POTENCIES: 80 mg, 120 mg, 160 mg and 240 mg

15. CHEMICAL NAME AND STRUCTURE

Sotalol Hydrochloride. Methanesulfonamide, *N*-[4-[1-hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl]-, monohydrochloride. $C_{12}H_{20}N_2O_3S\$HCl$. M.W. = 308.82. CAS 959-24-0.



16. RECORDS AND REPORTS N/A

17. COMMENTS
Eon responds to our concerns dated 3/10/00:
(All Acceptable)

Q1. Regarding the updated specification for Lactose , it is noted that ' is not listed as one of the test parameters. Please clarify.

A1. l, the manufacturer of lactose, has provided a letter (Attachment 1) stating that they make no claims in their product labeling regarding the content of for their lactose products. Therefore, they are not required to test for for their lactose product.

Q2. Please provide information to demonstrate the equivalency of the new proposed liner for the 100 count.

A2. An illustration is included which demonstrates the equivalency of the old and new liner/innerseal system for the 100 count. Technical data from comparing the two are submitted (Attachment 2).

Q3. Regarding the alternate bottle, please update page 741 of your original submission to reflect its use.

A3. The revision including an alternate bottle is provided in Attachment 3. The alternate bottle will be manufactured by using resin. Information relevant to the alternate bottle which includes a DMF referral letter and a technical data sheet is submitted.

Q4. You need to provide stability data for the 80 mg tablet in 500 count.

Q5. Please provide new labeling information to reflect the addition of 500's package for the 80 mg tablet.

A4. & A5.
Firm is withdrawing the 500 count for the 80 mg tablet at this time.

Status Summary:

DMF:	DMF acceptable (4/27/99)
Labeling:	Satisfactory (9/20/99)
Microbiology:	N/A
EER:	Acceptable 7/23/99
Sample:	Acceptable (see section 31)
Bio:	Satisfactory (10/27/98)

18. CONCLUSIONS AND RECOMMENDATIONS
Approval recommended

19. REVIEWER: DATE COMPLETED:
Maria C. Shih 4/3/00

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev. 6

4/3/00